REMARKS

This Amendment is responsive to the Office Action dated August 18, 2009. Applicant has amended claims 1, 20, 29, 35, and 36. Support for the Applicant's amendment to independent claims 1, 29, 35, and 36 can be found in Applicant's Specification, e.g., at paragraph [0068], [0073], and [0079]. Claim 19 has been canceled. Claims 37 and 38 have been added. Claims 1-9, 11-18, 20-31, and 33-38 are pending.

Information Disclosure Statement

Applicant would like to point out that the Examiner does not appear to have considered all references listed in the 1449 form that accompanied the Information Disclosure Statement filed on July 21, 2009. In particular, Applicant notes that the Supplemental European Search Report dated May 8, 2009 for corresponding European Patent Application 01973465.6-1265 was lined through in the copy of the 1449 form supplied by the Examiner. Applicant respectfully requests that the Examiner consider all references listed in the Information Disclosure Statement and provide an initialed copy of the 1449 form indicating that all references have been considered along with the next official action, or provide an explanation as to the reason the Examiner is not considering the Supplemental European Search Report.

Claim Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 1-3, 5, 7-9, 27-29, 31 and 34-36 under 35 U.S.C. 103(a) as being unpatentable over Cigaina (U.S. 5,423,872) in view of Douglas (U.S. 5,292,344). The Examiner also rejected claims 4, 6, 11-18 and 30 under 35 U.S.C. 103(a) as being unpatentable over Cigaina in view of Douglas and further in view of Gordon (U.S. 6,895,278).

Applicant respectfully traverses the rejection to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claims 1-3, 5, 7-9, 27-29, 31 and 34-36

Amended independent claim 1 requires a plurality of sensing electrodes for sensing intrinsic gastric activity from a stomach wall of a patient and an implantable gastric stimulator coupled to the plurality of sensing electrodes. The implantable gastric stimulator is configured to receive the sensed intrinsic gastric activity and perform an analysis of the sensed intrinsic gastric activity to classify the activity as normal or abnormal and determine whether to create an electrical stimulation based at least in part upon the classification of the sensed intrinsic gastric activity as normal or abnormal. The implantable gastric stimulator also delivers the electrical stimulation when the sensed intrinsic gastric activity is classified as normal. Claim 1 also requires a plurality of stimulation electrodes configured to convey the electrical stimulation from the implantable gastric stimulator to the stomach wall of the patient, wherein the electrical stimulation is configured to disrupt normal gastric activity of the stomach. Amended claim 1 additionally requires that the implantable gastric stimulator is configured to switch between any of a plurality of stimulation vectors each depending upon the sensed intrinsic gastric activity.

In the Office Action, with regard to independent claims 1, 29, 35 and 36, the Examiner stated (at Item 3) that:

> Cigaina discloses a gastric pacemaker that senses electrical activity and then provides "on demand" stimulation (Col. 3, ll. 41-45). Cigaina further discloses that the system stimulates to disrupt normal slow waves and prevent emptying of the stomach.

The Examiner further stated (at Item 5) that "Cigaina discloses a system that senses and then disrupts normal activity, [but] it is silent as to if the gastric pacemaker includes multiple electrodes." However, in view of this deficiency, the Examiner further stated that:

> Douglas discloses a gastric pacemaker that includes multiple electrodes for sensing and stimulating that are located through the stomach and connected to sensing and stimulation channels (Figs. 1 & 2A). Douglas further teaches how the electrodes are connected to the gastric pacemaker on one end and the stomach wall on the other end (FIG. 2A).

On this basis, the Examiner reasoned that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the gastrointestinal pacemaker of Cigaina with the multiple-electrode gastrointestinal pacemaker of Douglas in order to provide the predictable results of increasing the sensing and stimulation sites to provide increased control.

Applicant disagrees with the Examiner's conclusion in as much as it relates to amended independent claim 1. First, Cigaina does not teach or suggest classification of sensed intrinsic gastric activity as normal or abnormal. Second, none of the prior art of record contemplates that the implantable gastric stimulator is configured to switch between any of a plurality of stimulation vectors depending upon the sensed intrinsic gastric activity.

Contrary to the Examiner's assertion, Cigaina does not suggest the classification of sensed intrinsic gastric activity as normal or abnormal. As identified by the Examiner, Cigaina generally describes that "[t]he stimulator can be programmed for both continuous stimulation and for 'on demand' stimulation, i.e., at the onset of a particular electrical activity which can be detected by the stimulator itself through the electrocatheter."[1] In this manner, Cigaina only discloses delivering electrical stimulation to alter the natural gastric motility upon the onset of a particular detected electrical activity.

However, Cigaina fails to suggest that the stimulator analyzes the sensed intrinsic gastric activity to classify the activity as normal or abnormal. Cigaina fails entirely to describe the type of particular activity that triggers the on-demand stimulation, much less specify that normal intrinsic gastric activity triggers the on-demand stimulation. Cigaina also fails to suggest that the sensed electrical activity is unique to any particular type of stimulation delivered to the patient. Further, Cigaina fails to teach that any type or amount of analysis or classification occurs upon detecting this unidentified electrical activity. Accordingly, contrary to the features of independent claim 1, Cigaina is devoid of any suggestion that the stimulator analyzes the sensed intrinsic gastric activity to classify the activity as normal or abnormal.

In addition, Cigaina fails to teach or disclose the feature of the stimulator being configured to switch between any of a plurality of stimulation vectors depending upon the sensed intrinsic gastric activity. As acknowledged by the Examiner, Cigaina does not disclose a system with multiple electrodes.[2] Therefore, Cigaina cannot suggest switching between any of a plurality of stimulation vectors.

Furthermore, Douglas also fails to contemplate a stimulator configured to switch between any of a plurality of stimulation vectors depending upon the sensed intrinsic gastric activity. Douglas generally describes an electrical stimulation system for the gastrointestinal tract that

[1] Cigaina, col. 3, lines 41-45.
[2] Office Action, Page 2.

also senses the motor activity of the intestinal tract for feedback to the stimulation.[3] More specifically, Douglas discloses an adjustable electrical current source and an adjustable rate of the current pulses.[4]

However, contrary to the features of amended independent claim 1, Douglas does not disclose switching between any of a plurality of stimulation vectors, much less switching between any of a plurality of stimulation vectors depending upon the sensed intrinsic gastric activity. Indeed, while Douglas does describe multiple electrodes, Douglas simply teaches that "stimulative electrodes 312, 314, 316, 318 would be simultaneously fired through a conductive path through cable 310."[5] Consequently, Douglas does not appear to contemplate any electrode configuration or stimulation vectors beyond the simultaneous firing of electrodes 316, 316, 318. Accordingly, to at least the extent that Douglas fails to contemplate multiple stimulation vectors, Douglas also fails to teach or suggest that a stimulator is configured to switch between any of a plurality of stimulation vectors depending upon the sensed intrinsic gastric activity.

For at least the reasons outlined above, Cigaina fails to teach or suggest the features of amended independent claim 1. Moreover, Douglas fails to provide any teaching sufficient to overcome the deficiencies identified in Cigaina.

Amended independent claim 29 requires sensing intrinsic gastric activity on the stomach wall of a patient, classifying the sensed intrinsic gastric activity as normal or abnormal, and determining when to apply electrical stimulation to the stomach wall of the patient based upon the classification of the sensed intrinsic gastric activity as normal or abnormal. Claim 29 also requires selecting at least one of a plurality of stimulation vectors across the stomach wall for application of electrical stimulation based upon the sensed intrinsic gastric activity, forming an electrical signal in response to the determining when the sensed intrinsic gastric activity is classified as normal, and applying the electrical signal via the at least one selected stimulation vector to disrupt normal gastric activity of the stomach.

For at least the reasons previously identified with regard to independent claim 1, the applied references fail to teach or suggest the features of independent claim 29. For example, the applied references fail to teach or suggest classifying sensed intrinsic gastric activity as normal or abnormal and determining when to apply electrical stimulation to the stomach wall of the

[3] Douglas, Abstract.
[4] Douglas, Col. 3-4, ll. 67-2.
[5] Douglas, Col. 9, ll. 3-6.

patient based upon the classification of the sensed intrinsic gastric activity as normal or abnormal. In addition, the applied references fail to teach or suggest selecting at least one of a plurality of stimulation vectors across the stomach wall for application of electrical stimulation based upon the sensed intrinsic gastric activity.

Amended independent claim 35 requires a plurality of sensing electrodes for sensing intrinsic electrical gastric activity from a stomach wall of a patient, and an implantable gastric stimulator coupled to the sensing electrodes, where the implantable gastric stimulator receives the sensed intrinsic electrical gastric activity and classifies the activity as normal or abnormal, and where the stimulator creates electrical stimulation when the sensed intrinsic electrical gastric activity is classified as normal. Claim 35 also requires a plurality of stimulation electrodes for conveying the electrical stimulation from the implantable gastric stimulator to the stomach wall of the patient, where the electrical stimulation is configured to disrupt normal gastric activity of the stomach and the implantable gastric stimulator is configured to switch between any of a plurality of stimulation vectors based upon the sensed intrinsic electrical gastric activity.

For at least the reasons previously identified with regard to claims 1 and 29, the applied references fail to teach or suggest the features of independent claim 35. For example, the applied references fail to teach or suggest an implantable gastric stimulator that receives the sensed intrinsic electrical gastric activity and classifies the activity as normal or abnormal. Also, the applied references fail to contemplate an implantable gastric stimulator that is configured to switch between any of a plurality of stimulation vectors based upon the sensed intrinsic electrical gastric activity.

Amended independent claim 36 requires sensing intrinsic electrical gastric activity from a stomach wall of a patient, classifying the intrinsic electrical gastric activity as normal or abnormal, and selecting at least one of a plurality of stimulation vectors across the stomach wall to apply electrical stimulation to the patient based upon the sensed intrinsic electrical gastric activity. Claim 36 also requires applying electrical stimulation to the patient via the at least one selected stimulation vector when the intrinsic electrical gastric activity is classified as normal, where the electrical stimulation is configured to disrupt normal gastric activity of the stomach, and withholding application of electrical stimulation to the patient when the intrinsic electrical gastric activity is classified as abnormal.

For at least the reasons previously identified with regard to claims 1, 29, and 35, the applied references fail to teach or suggest the features of independent claim 36. For example, the applied references fail to teach or suggest sensing intrinsic electrical gastric activity from a stomach wall of a patient and classifying the intrinsic electrical gastric activity as normal or abnormal. Also, the applied references fail to contemplate determining which of a plurality of stimulation vectors across the stomach wall to apply electrical stimulation to the patient based upon the sensed intrinsic electrical gastric activity.

Moreover, the applied references fail to teach or suggest withholding application of electrical stimulation to the patient when the intrinsic electrical gastric activity is classified as abnormal, as required by claim 36. Indeed, to at least the extent that Cigaina fails to teach or disclose classifying sensed intrinsic electric activity as normal or abnormal, it follows that Cigaina fails to describe withholding application of stimulation when the intrinsic electrical gastric activity is classified as abnormal. By applying the electrical stimulation to the patient when the intrinsic electrical gastric activity is classified as normal and withholding electrical stimulation when intrinsic electrical gastric activity is classified as abnormal, such a technique may ensure that normal intrinsic electrical activity of a patient is disrupted without unnecessarily delivering electrical stimulation to the patient when abnormal electrical activity of is sensed.

Dependent claims 2, 3, 7-9, 27, 28, 31 and 34 are allowable for at least the reasons put forth above with respect to independent claims 1 and 29, from which they depend. Therefore, the applied references fail to teach or suggest the features claims 2, 3, 7-9, 27, 28, 31 and 34.

In addition to the deficiencies identified with respect to independent claims 1 and 29, the applied references also fail to teach or suggest the additional features of the various dependent claims. For example, the applied references fail to teach or suggest analyzing the sensed intrinsic gastric activity and classifying the sensed intrinsic gastric activity as a slow wave or a peristaltic wave, as required by dependent claims 9 and 31.

Claims 4, 6, 11-18 and 30

Dependent claims 4, 6, 11-18 and 30 are allowable for at least the reasons put forth above with respect to independent claims 1 and 29, from which they depend. For the reasons previously stated, Cigaina and Douglas, viewed in combination or individually, do not disclose or suggest all features of amended independent claims 1 and 29 and, therefore, does not teach or

disclose all features of claims 4, 6, 11–18 and 30. Furthermore, these identified deficiencies are not overcome by the teachings of Gordon.

In addition, Gordon, in combination with Cigaina and Douglas, also fails to teach or suggest the features of the various dependent claims. For example, the applied references fail to teach or suggest the feature of the stimulator temporarily reverting to a power conserve condition in the absence of a programmable threshold of normal activity, as required by claim 11.

While Gordon describes using a programmable calendar 48 in FIG. 3 to provide increased stimulation at certain hours of the day, and decreased stimulation at other hours of the day, the specific times of providing decreased stimulation appear to be preprogrammed times based on when gastric activity is estimated to be less than other times of the day.[6] On the contrary, claim 11 requires that the stimulator revert to a power conservation condition in the absence of a programmable threshold of normal activity, rather than preprogrammed time periods as described by Gordon.

As another example, the applied references fail to teach or suggest the features of dependent claims 14-18. Indeed, the applied references fail to teach or suggest that the electrical stimulation is delivered: across the sensed intrinsic gastric activity, as required by claim 14; with a spatial offset to the sensed intrinsic gastric activity, as required by claim 15; with a temporal offset to the sensed intrinsic gastric activity, as required by claim 16; or in anticipation of the next normal electrical activity, as required by claim 17.

Applicant believes that the Examiner is misinterpreting the claimed invention. In rejecting claims 14-18, the Examiner suggested that Douglas discloses that the stimulation is offset or direct, and that it would be preferable to stimulate the stomach "directly or indirectly" to provide increased disruption of the normal waves.[7] However, none of claims 14-18 require "direct" or "indirect" stimulation.

Nonetheless, Douglass still does not teach or suggest any of the features of claims 14-18. Although Douglas discloses that the frequency and voltage of stimulation pulses may be controlled, Douglas does not suggest that stimulation is delivered with a temporal offset to the sensed intrinsic gastric activity, for the example of claim 16. Applicant respectfully requests that the Examiner withdraw the rejection of claims 14-18.

[6] *See* Gordon, column 10, line 44 to column 11, line 41.
[7] Office Action, Page 4.

As another example, contrary to the Examiner's argument, Gordon fails to teach or disclose maintaining a history of predecessor electrical events, as required by claim 30. While Gordon describes a device including a memory provided to store data,[8] Gordon makes no mention of maintaining a history of predecessor events, much less predecessor electrical events.

For at least the foregoing reasons, Applicant's claims 1-9, 11-18, 20-31, and 33-36 are patentable over the applied references under 35 U.S.C. § 103(a). Reconsideration and withdrawal of the rejection of claims 1-9, 11-18, 20-31, and 33-36 are respectfully requested.

New Claims

Applicant has added claims 37 and 38 to the pending application. As discussed below, independent claim 37 incorporates claims previously indicated as allowable by the Examiner.

In regard to dependent claim 38, the applied references fail to disclose or suggest the inventions defined by Applicant's new claim, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. Neither Cigaina nor Douglas disclose or suggest that a stimulator employs a neural network to classify the sensed intrinsic gastric activity, as required by claim 38. Support for the features of claim 38 can be found in Applicant's Specification on page 16, lines 12-21, for example. No new matter has been added by the new claims.

Allowable Subject Matter

In the Office Action, the Examiner indicated that claims 19-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim. Applicant appreciates the Examiner's indication that claims 19-26 are allowable subject matter if rewritten in independent form.

Applicant has added new claim 37, which incorporates each and every element of former independent claim 1 and former allowable claim 19 (including intervening dependent claims 11-13). Dependent claims 20-26 are now dependent upon new independent claim 37. Independent claim 37 and dependent claims 20-26 are in condition for allowance.

[8] Gordon, column 5, lines 1-3.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 11/18/09

By: _____

SHUMAKER & SIEFFERT, P.A.
1625 Radio Drive, Suite 300
Woodbury, Minnesota 55125
Telephone: 651.286.8352
Facsimile: 651.735.1102

Name: Jeffrey D. Wilford
Reg. No.: 63,926